CHPA

founded 1881

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CHPA Comments on House Bill 4318

Members of the Judiciary Committee:

Thank you for the opportunity to comment on H.B. 4318. The Consumer Healthcare Products Associations (CHPA) is the 128-year-old trade association representing manufacturers of over-the-counter (OTC) medicines. H.B. 4318 provides that it is unlawful for a manufacturer to fail to accurately represent the risks associated with an over-the-counter (nonprescription) medicine.

CHPA strongly opposes this provision because the Federal Food, Drug, and Cosmetic Act specifically prohibits states from establishing different requirements for nonprescription medicines than those found in federal law (21 U.S.C. 379r). U.S. Food and Drug Administration regulations and drug approvals clearly define the consumer information and warnings that manufacturers must provide on medicine labels.

Federally mandated warnings include, whenever applicable, circumstances under which a medicine should never be used, conditions or symptoms that require consultation with a doctor before using the medicine, information about drug/drug and drug/food interactions, side effects, activities to avoid when taking a medicine, and signs of serious reactions that require a consumer to stop using a medicine.

H.B. 4318 would create a state requirement regarding drug warnings, as determined by state regulators, and therefore is preempted by federal statute. Further, it would create an unfair and uncertain business environment to allow state regulators to determine on a case-by-case basis whether a drug label accurately represents risks associated with a drug, and to bring punitive actions against a manufacturer who actually is in full compliance with federal law.

For these reasons, CHPA opposes H.B. 4318.

Respectfully submitted by Mandy Hagan, Director, State Government Relations

Consumer Healthcare Products Association
900 19th Street, NW, Suite 700
Washington, DC 20006
T 202.429.9260 F 202.223.6835
www.chpa-info.org